

REMARKS/ARGUMENTS

Favorable reconsideration of this application as presently amended and in light of the following discussion is respectfully requested.

Claims 9-17 are now pending in this application. Claims 9-15 and 17 are herein amended to place the claims in better condition. No substantive changes are made and no new matter is added.

In the outstanding Office Action, Claims 9 and 15 were rejected under 35 U.S.C. § 102(e) as anticipated by Rizvi, U.S. Patent No. 6,168,611. Claims 10 and 13-17 were rejected under 35 U.S.C. § 103(a) as obvious over Rizvi in view of Aiyama, U.S. Patent No. 5,669,101. Claims 11 and 12 were indicated as allowable, but objected to as depending from a rejected base claim. Applicants thank the Office for its indication of allowable subject matter.

Claims 9 and 15 were rejected under 35 U.S.C. § 102(e) as anticipated by Rizvi. Applicants respectfully request withdrawal of these rejections as the Office has failed to state a prima facie case of anticipation. Rizvi simply fails to teach or suggest all of the limitations of claims 9 and 15.

Claim 9 is directed to a surgical needle combination for implanting a sling. The needle combination includes an elongate arcuate needle that is sized and shaped to withstand forces encountered during a sling implantation procedure, with the needle having first and second ends. The combination also includes a means for associating the needle with a sling, a first handle associated with an end of the needle, and a second handle which is separate from the first handle and situated along the needle.

Claim 15 is directed to a method of implanting a sling. The method includes a step of providing an elongate arcuate needle that is sized and shaped to withstand forces encountered during a sling implantation procedure, with the needle having first and second ends. The

method also includes providing a means for associating the needle with a sling, a first handle associated with an end of the needle, and a second handle which is separate from the first handle and situated along the needle. The method further includes inserting the end of the needle that is opposite the first handle into the tissue of the patient and passing the needle through the tissue of the patient by grasping either the first or second handle, the needle or any combination thereof, in order to control the passage of the needle into the patient's tissue.

It is clear that claims 9 and 15 require that the needle is arcuate and that the needle combination has two handles. Despite the assertions of the Office to the contrary, Rizvi neither teaches nor suggests either of these limitations.

Claims 9 and 15 require that the needle be arcuate. The present specification defines this limitation further, noting at page 36, line 24 that "the needle 60 is generally curved or arc-shaped", referring to Figure 16A, which clearly shows a curved needle. Further, one skilled in the art would have understood arcuate to mean "formed in the shape of an arc". See AMERICAN HERITAGE STEDMAN'S MEDICAL DICTIONARY, 2002, as found at <www.dictionary.com> (attached as Exhibit 1). On the other hand, Rizvi discloses a needle that is clearly not arcuate. This is evidenced by its specification at col. 4, lines 34-64:

Needle body 52 defines a first **straight** portion 72 adjacent to first end 56 and a second **straight** portion 74 connected to first **straight** portion 72 and adjacent to second end 58. First and second **straight** portions 72, 74 define an angle 75 therebetween of from one hundred ten degrees to one hundred eighty degrees, but preferably one hundred forty-five degrees. Needle assembly 50 is preferably made from stainless steel.

A second needle assembly embodiment 50' is shown in FIGS. 5-8A. Needle assembly 50' comprises a hollow, elongated needle body 52' which defines a first **straight** portion 76 adjacent to first end 78. Needle body 52' further defines a second **straight** portion 80 adjacent to second end 82. Needle body 52' further defines a third **straight** portion 84 connected to first **straight** portion 76 and a fourth **straight** portion 86 connected between portions 80 and 84. Fourth portion 86 defines first and second angles 88, 90 with each of **straight** portions 80, 84, respectively. Angles 88, 90 are from one hundred fifteen degrees to one hundred seventy-five degrees but preferably one hundred forty-five degrees, and angles 88, 90 are equal to each other.

First and third **straight** portions 76, 84 define a third angle 92 therebetween of from one hundred five degrees to one hundred sixty-five degrees but preferably one hundred thirty-five degrees.

Needle assembly 50' is preferably configured wherein second **straight** portion 80 defines an extended imaginary straight center line therethrough (not shown) which intersects with first **straight** portion 76. This configuration is best seen in FIG. 6.

Straight is not arcuate. A needle which is made up of multiple straight portions that are connected together at angles does not constitute an arcuate needle. No rounded or curved or bowed or arcuate needle is disclosed or suggested by Rizvi.

Rizvi doesn't disclose an arcuate needle. Nor does it disclose or suggest a second handle. The Office asserts that element 62 in Fig. 8, as seen in Figure 8 of Rizvi, is the first handle of the present invention, with element 68 representing the second handle. Clearly, element 68 is a handle. However, there is no teaching or suggestion of two handles on the needle of Rizvi. There is no suggestion that element 62 is or can be used as a handle. Instead, element 62 is obviously a fitting for attachment to a source of local anesthetic. Col. 5, lines 13-15. It is a connector for tubing. It is not a handle. The Federal Circuit has required that the words of a claim be given their ordinary meaning as interpreted by one skilled in the art. *Phillips v. AWH Corporation*, 415 F.3d 1303,1313 (Fed. Cir. 2005). Applicants submit that no person of skill in the art would have interpreted the connector in the Rizvi patent as a handle. Rizvi utterly fails to teach or suggest a second handle.

Failing to teach or suggest a needle combination including a needle that is arcuate or a combination having two handles, as required by claims 9 and 15, Applicants respectfully request the withdrawal of the rejections of claims 9 and 15 as anticipated by Rizvi.

Claims 10 and 13-17 were rejected under 35 U.S.C. § 103(a) as obvious over Rizvi in view of Aiyama, U.S. Patent No. 5,669,101. Claims 10 and 13-16 depend from either claims 9 or 15, and thus require that the needle be arcuate and that the combination has two handles.

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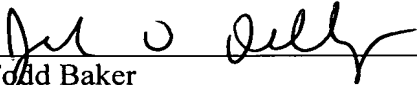
Claim 17, like claims 9 and 15, include the same limitations. As noted above, Rizvi fails to teach or suggest these limitations. Aiyama clearly does nothing to remedy the deficiencies of Rizvi. Failing to teach or suggest all the limitations of the claims, Rizvi and Aiyama cannot render claims 10 and 13-17 obvious. Accordingly, Applicants respectfully request the withdrawal of these rejections.

Applicants have herein amended the specification to clarify that the present application is a continuation of U.S. Patent Application 09/917,445. Applicants note that this status was indicated in the Application Data Sheet submitted on the filing date of the present application, and this status was acknowledged in Filing Receipt received from the Patent Office on October 15, 2003. Copies of the Application Data Sheet and the Filing Receipt are attached as Exhibit 2.

In light of the above discussion and the present amendment, the present application is believed to be in condition for allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

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